

### **REMARKS**

The claims are 15-22 and 25-41 with claims 15 and 34 being independent. Claims 15 and 34 have been amended to remove the parenthetical term "(XRPD)". Claims 15-34 have been amended to change the phrase "a polymorph" to --a compound-- and to otherwise read in better form. Support for claims 36-41 may be found in the specification at page 2, lines 23-27 and in Examples 2 and 3 at page 7. No new matter has been added. Claims 23 and 24 have been cancelled without prejudice or disclaimer. Accordingly any objections to claims 23 and 24 have been rendered moot. The cancelled claims are 1-14, 23 and 24.

The Examiner has objected to claims 16-21 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for reciting the limitation of a figure or a table. Applicants respectfully submit that M.P.E.P. 2173.05(s) provides full support for drafting claims 16-21 to incorporate by reference to a specific figure or table, where, as in this case, "there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim." Applicants respectfully request withdrawal of the formal objections to claims 16-21.

The Examiner has also objected to the term "isolated" in claim 22 as allegedly indefinite. Applicants respectfully submit that the use of the term "isolated" in the context of the present invention is well understood and commonly used in the art. A chemical definition of the term "isolated" from The American Heritage<sup>®</sup> Dictionary of the English Language: Fourth Edition, 2000, is "to separate (a substance) in pure form from a combined mixture." The Examiner questions "How isolated is the polymorph?" Applicants respectfully submit that any restriction on the term "isolated" implies that the compound is not isolated but is admixed with other compounds, solvents or materials. Accordingly, when the term "isolated" is used to describe the compound of claim 22, the term indicates that only the solid maleate polymorph is present and that no other compounds, solvents or materials are admixed therewith. Based on the doctrine of claim differentiation, this further indicates that the compound described in claim 15 (and claim 34) may be isolated or may be present as a mixture with other compounds, solvents or materials. Applicants respectfully submit that the term "isolated" in the context of the present invention is not indefinite and, accordingly, respectfully request withdrawal of the objection to claim 22.

Claims 15-24, 27, 32, 33 and 34 have been rejected under 35 U.S.C. §103 as allegedly unpatentable over Patel et al. The Examiner contends that it would have been allegedly obvious to create a polymorph of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione maleic acid salt. Applicants respectfully traverse this rejection.

Applicants respectfully submit that the 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione maleic acid salt polymorph defined in the present invention is unique - the existence, structure and properties of which were unknown and unpredictable.

Contrary to the Examiner's assertion, Applicants respectfully submit that no "unexpected results" need to be demonstrated to establish the patentability of the novel polymorph defined in the pending claims. In considering the patentability of new crystal forms, courts have not required a showing of unexpected results. In *Bristol-Myers Co. v. U.S. International Trade Commission*, 15 USPQ 2d 1258, 1261 (Fed. Cir. 1989), the court stated that when determining the obviousness of a new chemical structure, "[t]he question is whether it would have been obvious to make the [new crystal form], based on the prior art." The Court went on to state that "[t]here must be an affirmative suggestion or teaching in the prior art whereby it would have been obvious to make the new [form]; not simply the absence of obstacle." (emphasis added) *Id.* at 1262.

Moreover, as quoted in *Bristol-Myers Co. v. U.S. International Trade Commission*, 15 USPQ 2d 1258, 1261 (Fed. Cir. 1989), "[i]n factual and legal point is *In re Cofer*, 354 F.2d 664, 668, 148 USPQ 268, 271 (CCPA 1966), wherein the court held that a new crystalline form of a compound would not have been obvious absent evidence that 'the prior art suggests the particular structure or form of the compound or composition as well as suitable methods of obtaining that structure or form.'" (emphasis added)

Although Patel encompasses compositions containing all forms (polymorphs, hydrates, etc.) of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione maleate, as well as methods for preparing and using such compositions, Applicants respectfully submit that Patel fails to suggest under 35 U.S.C. § 103, not only the form of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione maleate that provides the IR, Raman, solid state <sup>13</sup>C and/or XRPD spectral peaks as defined in claims 15 and 34, but also fails to suggest any process by which the claimed maleate polymorph could be prepared.

Accordingly, Applicants respectfully submit that the claimed polymorph of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione maleic acid salt, is patentable over the disclosure of Patel. In addition, Applicants respectfully submit that the process of preparing the claimed polymorph and the uses thereof are also patentable over the disclosure of Patel.

In view of the foregoing amendments and remarks, Applicants respectfully submit that the subject application is in condition for allowance. If the Examiner has any remaining objections or concerns, the Examiner is respectfully requested to contact Applicants' undersigned attorney to resolve such issues and advance the case to issue.